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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,673	06/03/2002	Howard Green	H0535/7014	6874

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EXAMINER	
HANLEY, SUSAN MARIE	
ART UNIT	PAPER NUMBER
1651	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/031,673	GREEN ET AL.	
	Examiner	Art Unit	
	Susan Hanley	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,24,36,51,95-104 and 106-118* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10, 24, 36, 51, 95-104 and 106-118* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and reply filed 11/22/06 are acknowledged.

Claims 1-10, 24, 36, 51, 95-104 and 106-118 are under examination.

Claim Rejections - 35 USC § 102

Claim 36 stands rejected under 35 U.S.C. 102(b) as being clearly anticipated by Urry (US 4,589,882; cited in previous Office action).

Applicant argues that the bioelastomers taught by Urry can be polypeptides strengthened with core fibers and that said bioelastomers constitute only an active agent and not a conjugate of an active agent and a linker, as claimed.

Applicant's arguments filed 11/22/06 have been fully considered but they are not persuasive. Responding to Applicant's argument that Urry's bioelastomers provide only an active agent and not a conjugate of an active agent and a linker, Urry teaches that the elastomer by itself is an active agent and that the disclosed conjugated bioelastomeric polypeptides constitute an improved agent (col. 11, lines 14-26). Urry teaches that the bioelastomer serves as an in vivo substrate for lysine oxidase. Lysine oxidase will inherently attach the bioelastomer of Urry to tissue via the polypeptide. Thus, the polypeptide of the bioelastomer serves two functions: 1) as a means of increasing the strength of the elastomer and 2) as a linker for attachment to tissue in vivo. can be bonded to a material that imparts strength to the elastic fibers. The limitations of claim 36 do not exclude that the polypeptide linker has some positive value in increasing the efficacy of the active agent.

Claim Rejections - 35 USC § 103

Claims 1-3, 36, 98-101, and 118 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Richardson et al. (US 5,490,980) in view of Stedronsky (US 6,258,872; cited in previous Office action) and Urry (US 4,589,882).

Applicant argues that the Examiner has merely asserted that one of ordinary skill in the art would have been motivated to employ lysine oxidase instead of TGase for cross-linking the alkylamine-modified agents to human tissue in the method of Richardson et al. based on assertion that the enzymes serve the same purpose. Applicant asserts that Richardson et al. do not mention lysine oxidase even though it was known and did not consider the substitution. Applicant argues that the Examiner has not made a case for a reasonable expectation of success for the substitution of lysine oxidase for transglutaminase in the method of Richardson et al. Applicant asserts that Urry teaches away from the substitution because Urry teaches that "not all lysine-containing peptides are capable or acting as substrates of lysyl oxidase."

Applicant's arguments filed 11/22/06 have been fully considered but they are not persuasive. Responding to Applicant's argument tht Richardson et al. do not suggest the use of lysine oxidase, there is no requirement that motivation must be expressed in the base reference for a rejection based on 35 USC § 103. If that were the case, the based reference could be rejected based on anticipation. Stedronsky provides proper motivation because he teaches that lysine oxidase and transglutaminase are both suitable for enhancing the mechanical performance of tissue adhesives and sealants (referred to as adhesive/sealant) in damaged tissue by inserting a primer molecule between said tissue and the adhesive/sealant which is a protein or synthetic polymer (col. 8, lines 33-41). The ordinary artisan would have realized that this constitutes art recognition that the two enzyme are equivalent for the linkage of damaged tissue to adhesive/sealant (protein or synthetic polymer) via a primer molecule. Furthermore, the ordinary artisan would have realized that said linkage is analogous to the method of Richardson et al. as well as the instant invention, wherein the adhesive/sealant and primer molecule correspond to the active agent and the linker, respectively of the instant application.

Responding to Applicant's argument that that the Examiner has not made a case for a reasonable expectation of success for the substitution of lysine oxidase for transglutaminase in the method of Richardson et al., Applicant is ignoring the teaching of Stedronsky which *specifically* discloses that lysine

oxidase and transglutaminase are both suitable tissue/agent cross-linking enzymes. Regarding the Assertion that Urry teaches away from the claimed invention, Richardson et al. and Urry teach that transglutaminase and lysine oxidase catalyze cross-linking when the alkyl portion of the lysine is 2-8 carbons (Richardson, col. 2, lines 25-35 and Urry, col. 8, lines 3-30). Therefore, the ordinary artisan would clearly have had a reasonable expectation that one could substitute lysyl oxidase for transglutaminase in the method of Richardson, and thus arrive at the claimed invention.

Double Patenting

Claims 1-10, 24, 36, 51, 95-104 and 108 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-46 and 48 of U.S. Patent No. 6,267,957 in view of Stedronsky (US 6,258,872), Urry (US 4,589,882), and Webster's Dictionary (p. 857; cited in the previous Office action).

Applicant argues that the examiner has not demonstrated motivation or a reasonable expectation of success to substitute transglutaminase with lysine oxidase expectation of success based on the arguments presented *supra.*

Applicant's arguments filed 11/22/06 have been fully considered but they are not persuasive for the reasons stated in the rebuttal to the rejection based on 35 USC § 103.

Claims 1-10, 24, 36, 51, 95-104 and 106-118 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-52 of copending Application No. 11/144,372 in view of Stedronsky (US 6,258,872), Urry (US 4,589,882), and Webster's Dictionary (p. 857; cited in the previous Office action).

Applicant argues that the examiner has not demonstrated motivation or a reasonable expectation of success to substitute transglutaminase with lysine oxidase expectation of success based on the

arguments presented *supra*. Applicant notes that the rejection is provisional and maintains the right to address the rejection in the future.

Applicant's arguments filed 11/22/06 have been fully considered but they are not persuasive for the reasons stated in the rebuttal to the rejection based on 35 USC § 103.

Claims 1-10, 24, 36, 51, 95-104 and 106-118 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-50 of copending Application No. 11/125,830 in view of Stedronsky (US 6,258,872) and Urry (US 4,589,882).

Applicant argues that the examiner has not demonstrated motivation or a reasonable expectation of success to substitute transglutaminase with lysine oxidase expectation of success based on the arguments presented *supra*. Applicant notes that the rejection is provisional and maintains the right to address the rejection in the future.

Applicant's arguments filed 11/22/06 have been fully considered but they are not persuasive for the reasons stated in the rebuttal to the rejection based on 35 USC § 103.

Claims 1-10, 24, 36, 51, 95-104 and 106-118 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22, 25, 145-152, 155, 156, 158-165 and 167-173 of U.S. Patent 6,958,148 (Application No. 09/620,783) in view of Stedronsky (US 6,258,872) and Urry (US 4,589,882).

Applicant argues that the examiner has not demonstrated motivation or a reasonable expectation of success to substitute transglutaminase with lysine oxidase expectation of success based on the arguments presented *supra*.

Applicant's arguments filed 11/22/06 have been fully considered but they are not persuasive for the reasons stated in the rebuttal to the rejection based on 35 USC § 103.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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